May 22, 2003

THIS EVENT IS NOT FOR PUBLIC DISCLOSURE PER AGREEMENT STATE REQUEST UNTIL 5/23/2003.

PRELIMINARY NOTIFICATION OF EVENT OR UNUSUAL OCCURRENCE -- PNO-IV-03-028

This preliminary notification constitutes EARLY notice of events of POSSIBLE safety or public interest significance. The information is as initially received without verification or evaluation, and is basically all that is known by the Region IV staff on this date.

Facility
Oklahoma University Medical Center
Oklahoma City, Oklahoma
License No.: OK-21035-01
Oklahoma Agreement State Licensee

Licensee Emergency Classification
___ Notification of Unusual Event
___ Alert
___ Site Area Emergency
___ General Emergency
_X_ Not Applicable

SUBJECT: MEDICAL MISADMINISTRATION

DESCRIPTION: On May 20, 2003, the Oklahoma Department of Environmental Quality (the Department) notified NRC's Operations Center of a reported medical misadministration involving iridium-192 in a high dose-rate remote afterloader (HDR) and a MammoSite® Radiation Therapy System. The event is a medical misadministration based on Oklahoma's current regulation for the medical use of radioactive material.

Oklahoma University Medical Center, an Oklahoma licensee, notified the Department of the potential misadministration on May 5, 2003. The licensee reported that the patient was prescribed ten fractions, 340 centigray each, using an HDR brachytherapy unit, containing 305.8 gigabequerels (8.3 curies) of iridium-192. The MammoSite® Radiation Therapy System was used to deliver the intracavitary radiation treatment for breast cancer after a lumpectomy. The catheter consisted of a tube with a balloon assembly at the distal end which was implanted in the tumor cavity. The iridium source, connected to the HDR unit, was inserted into the balloon to deliver the prescribed dose of radiation. Upon administering the first fraction, the licensee noticed that the iridium source did not reach the center of the balloon. It was determined that the source was approximately 30 millimeters from the center. The licensee had used radiographic and computed tomography (CT) images to determine the anatomical placement of the balloon. However, the patient's orientation in the CT was rotated 180 degrees compared to the radiographic image. The licensee, inadvertently, used the CT image to generate the treatment plan which resulted in the treatment error. The treatment resulted in an estimated dose of 190 centigray delivered to the target. The licensee is evaluating the dose delivered to the unintended site. The referring physician and patient have been notified. No adverse effects are anticipated. The licensee has implemented a number of corrective actions. The Department is continuing to investigate this event.

Region IV received notification of this occurrence from NRC's Operations Center at 8:00 p.m (CDT) on May 20, 2003. Region IV has informed OEDO, NMSS, OSTP, and the Region's SLO and PAO.

This information has been discussed with the licensee and is current as of 9:45 a.m. (CDT) on May 22, 2003.

CONTACTS: Vivian Campbell 817-860-8143
Elmo Collins 817-860-8106